UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge

TPP TRIAL DEFENDANTS' OMNIBUS STATEMENT OF MATERIAL FACTS NOT IN DISPUTE

Pursuant to Local Civ. Rule 56.1(a), the undersigned Third-Party Payor ("TPP") Trial Defendants[1] hereby furnish their statement of materials facts as to which there does not exist a genuine issue.[2]

A. The Voluntary Recall Of The At-Issue VCDs.

1. This case is a class action brought by named plaintiff and class representative MSP Recovery Claims, Series LLC ("MSP"), which asserts claims assigned to it by two TPPs—Group Health Incorporated and Health Insurance Plan of Greater New York ("Emblem") and Summacare, Inc. ("SummaCare"). (ECF 2261 (Class Certification Order) § 4.2.3; ECF 1708 (Third Am. Consol. Econ. Loss Cl. Action Compl.) ("Complaint" or "Compl.") ¶¶ 63-64.)

[1] The "TPP Trial Defendants" are: (i) Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP"), Huahai U.S., Inc. ("Huahai"), Prinston Pharmaceutical Inc. ("Prinston"), and Solco Healthcare U.S., LLC ("Solco") (collectively, "the ZHP Defendants"); (ii) Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Actavis LLC, and Actavis Pharma, Inc. (collectively, "the Teva Defendants" or "Teva"); and (iii) Torrent Pharmaceuticals Ltd. and Torrent Pharma, Inc. (collectively, "the Torrent Defendants" or "Torrent").

[2] The TPP Trial Defendants' Omnibus Motion for Summary Judgment concerns the claims designated in the Court's Case Management Order No. 32 (the "TPP Trial Claims"); specifically, the claims of Plaintiff MSP Recovery Claims, Series LLC, as class representative of TPP Breach of Warranty Subclass Group b, TPP Breach of Implied Warranty Subclass Group d, TPP Fraud Subclass Group c, and TPP State Consumer Protection Laws Subclass Group a (collectively, the "TPP Classes"), against the TPP Trial Defendants. (ECF 2343 at 1-2.) Accordingly, this statement of material facts not in dispute is limited to those facts that are material to the TPP Trial Claims, and is presented without waiver of any facts that may be material to any other claims asserted by any Plaintiff as to any Defendant(s) in this multi-district litigation.

2. MSP alleges that Emblem, SummaCare and the TPP class members are entitled to recover any and all money spent on their insureds' prescriptions for certain valsartan-containing drugs, alone or in combination with other anti-hypertensive medications (collectively, "valsartan-containing drugs" or "VCDs") (*see, e.g.*, Compl. ¶¶ 619-69), that were voluntarily recalled beginning in July 2018 due to the detection of N-Nitrosodimethylamine ("NDMA") in the VCDs. (*See* Ex. 1,[3] FDA News Release, July 13, 2018 "FDA Announces Voluntary Recall of Several Medicines Containing Valsartan Following Detection of Impurity" ("July 13 FDA News Release"); Ex. 2, SOLCO00000173.)

3. ZHP manufactured the active pharmaceutical ingredient ("API") used in certain recalled VCDs but did not market, sell or hold an Abbreviated New Drug Application ("ANDA") for any of the recalled VCDs.[4] ZHP's indirect subsidiary Prinston d/b/a Solco[5] manufactured and sold approximately 16 finished-dose VCDs with unique National Drug Codes ("NDCs") using ZHP's API that were included in

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[3] All exhibits to this Statement of Material Facts Not In Dispute are attached to the Certification of Jessica Davidson, submitted herewith.

[4] Huahai is a subsidiary of ZHP that is located in the United States. (Ex. 3, Deposition of Hai Wang ("Wang Dep.") 32:4-33:1, Mar. 10, 2021.) Like ZHP, Huahai did not manufacture, sell or hold an ANDA for any finished-dose VCD.

[5] Solco is wholly owned by Prinston (Ex. 4, Deposition of Jun Du 41:15-22, May 27, 2021) and was responsible for marketing, selling and labeling the recalled VCDs, for which Prinston held the ANDAs (*id.*; *see also* Wang Dep. 217:23-218:12).

the recall. (*See* Ex. 5, "Search List of Recalled Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan FDA.xlsx" ("Conti's Relevant Product List"), Ex. 6, Declartion of Rena Conti, Nov. 10, 2021.)

4. Three of the Teva Defendants manufactured and sold approximately 36 finished-dose VCDs with unique NDCs using ZHP's API that were included in the recall. (Ex. 6, Conti's Relevant Product List.) The fourth Teva Defendant, Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), is an Israeli corporation headquartered in Israel. (Compl. ¶ 99; ECF 2548 (Teva Ans. To Third Am. Consol. Econ. Loss Cl. Action Compl.) ¶ 99.) Teva Ltd. did not manufacture, sell, or ship any of the valsartan products included in the recall. (Ex. 7, Deposition of Michelle Osmian ("Osmian Dep.") 234:8-240:2, May 6, 2021 & Ex. 8 TEVA-230, May 6, 2021 (identifying the entities responsible for manufacturing, distributing and selling at-issue valsartan products).) These functions were at all times handled by the three other Teva Defendants: Teva Pharmaceuticals USA., Inc., Actavis LLC, and Actavis Pharma, Inc. (*Id.*)

5. The Torrent Defendants manufactured and sold approximately 12 finished-dose VCDs with unique NDCs using ZHP's API that were included in the recall. (Ex. 9, TORRENT-MDL2875-00165311.)

B. The Manufacturing Processes Used To Manufacture ZHP's Valsartan API.

6. On September 24, 2007, ZHP submitted the original Drug Master File for its "valsartan drug substance" to the FDA, which recorded it as Drug Master File No. 020939. (Ex. 10, ZHP01520766.) Drug Master File No. 020939 detailed ZHP's proposed manufacturing process for valsartan API, comprising a five-step route of synthesis (the "Valsartan ROS"). (Ex. 11, ZHP01661566 at 569-574.)

7. The Valsartan ROS outlined in Drug Master File No. 020939 used tributyl tin chloride as the catalyst for the reaction in Step 4. (*Id.* at 575.) The manufacturing process described in Drug Master File No. 020939 is referenced as the "Tin Process" herein. This Drug Master File is no longer active. (*See* Ex. 12, Amended Report of Dr. Ali Afnan, Ph.D. ("Afnan Rep.") ¶ 74, Jan. 11, 2023.)

8. ZHP subsequently elected to move away from the Tin Process and, on January 22, 2010, submitted Drug Master File No. 023491 for the "valsartan USP (process II)." (FDA, *List of Drug Master Files (DMFs): 3Q2022 Excel*, at Row 22636 (last updated 10/18/2022), https://www.fda.gov/media/159993/download (listing 1/22/2010 as the submission date of DMF No. 23491).) This Drug Master File is still "active" today. (*Id.*) Among other changes, Drug Master File No. 023491 substituted triethylamine hydrochloride for tributyl tin chloride in Step 4 of the Valsartan ROS. (*See* Ex. 13, ZHP01617328; Ex. 14, ZHP02231327 at 338.) The

manufacturing process described in Drug Master File No. 023491 is generally referenced herein as the "TEA Process."

9. On April 16, 2012, ZHP submitted Amendment-002 to Drug Master File No. 023491 ("Amendment 002"). (*See* Ex. 15, PRINSTON00071518.) Amendment-002 "add[ed] [a] quenching procedure after tetrazole [formation] reaction with sodium nitrite/HCl solution." (*Id.* at 522.) ZHP explained in its FDA filing that this change was made to limit the presence of a potentially dangerous substance known as azide, which was used in the TEA Process to optimize the tetrazole formation reaction. (*Id.* at 523.) However, "excess azide after [the] tetrazole [formation] reaction [would] introduce acidic azide gas with high toxicity and [raise] [Environmental Health & Safety] concern[s] during manufacturing." (*Id.* at 523.) To address the excess azide, ZHP proposed adding the quenching step "to guarantee [excess] azide [was] destroyed thoroughly and minimize the risk of residual azide carry-over into [the] final drug substance ([a] potential genotoxic impurity) and [the] environment." (*Id.*)

10. Prior to submitting Amendment-002, ZHP ran a number of tests to determine the effect, if any, that adding the quenching step would have on the manufacturing process. (*See* Ex. 16, ZHP01838512 at 517 (certified translation at 4) (noting that "[a]dding sodium nitrite quenching operation can effectively remove

azide ions in the reaction solution, and basically will not cause negative effects on product quality").)

11. Following Amendment-002, ZHP separated the TEA Process into two subcategories: the "TEA without quenching" process (original "Process II" prior to Amendment-002) and the "TEA with quenching" process, which referred to product made with the change identified in Amendment-002. (*See* Ex. 15, PRINSTON00071518 at 521-522 (listing changes in Amendment-002).)

12. On December 10, 2013, ZHP submitted Amendment-004 to Drug Master File No. 023491 ("Amendment 004"). (Ex. 17, ZHP01713711 (cover letter of submission).) Amendment 004 changed Step 3 of the Valsartan ROS by adding the common solvent dimethylformamide ("DMF" or "DMF solvent") to facilitate the reaction in that step. In addition, Amendment-004 also changed Step 4 of the Valsartan ROS by: (1) replacing triethylamine hydrochloride with zinc chloride as the catalyst reagent; (2) substituting DMF solvent for toluene as the solvent used in the reaction; and (3) adding methyl tertiary butyl ether ("MTBE") to facilitate the reaction in that step. (Ex. 18, PRINSTON00073102 at 104.) The manufacturing process documented in Amendment-004 is referenced herein as the "Zinc Chloride" process.

13. In its submission of Amendment-004 to the FDA, ZHP explained that it was adopting the Zinc Chloride process "to reduce racemization and waste for

quality (impurity A)" and to address an "EHS [Environment, Health & Safety] concern." (*Id.*) ZHP also noted that the substitution of zinc chloride for triethylamine hydrochloride as the applicable reagent provided satisfactory yields while lowering EHS and quality concerns. (*Id.* at 108.) ZHP further explained that testing showed that the new solvents DMF and MTBE, and the reagent zinc chloride, were all easily removable from the final product, and testing confirmed their absence in the final drug substance. (*Id.* at 113.)

14. The primary purpose of ZHP's changes to its manufacturing process "was to reduce impurity A in valsartan." (Ex. 19, Deposition of Linda Lin 209:2-210:5, May 5, 2021.)

C. The TPP Trial Defendants' Compliance With Regulatory Standards.

15. Current Good Manufacturing Practices ("cGMP") include standards set by the United States Pharmacopeia ("USP") and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH"). (Ex. 12, Afnan Rep. ¶ 18; *see also* 21 C.F.R. § 10.115(d)(1)-(3) (defining the legal authority of guidance from the FDA and, thus, ICH).)

16. ZHP's regulatory inspection history with the FDA reflects predominantly compliant findings with cGMP. (*See* Ex. 12, Afnan Rep. ¶¶ 92-94; *see also* FDA, Data Dashboard, https://datadashboard.fda.gov/ora/index.htm

(showing FDA inspections dating back to 2010 as "No Action Indicated" or "Voluntary Action Indicated").)

17. The sole Warning Letter ever issued to ZHP by the FDA as a result of ZHP's voluntary reporting of its NDMA discovery was resolved to the FDA's satisfaction and closed without any further enforcement action. (*See id.*; *see also* Ex. 20, ZHP02736709 (removing ZHP from FDA "Import Alert" 66-40 list); Ex. 21, ZHP02748991 (closing out warning letter).)

18. The Teva Defendants' manufacturing facilities received acceptable cGMP inspections from all regulators during the relevant time period, with no issues to which the presence of nitrosamine impurities may be attributed, and the FDA never issued any Warning Letters or put any hold on VCDs or other products manufactured in Teva's facilities for nitrosamine impurities. Teva's manufacture of its valsartan products conformed to all applicable cGMPs. (Ex. 22, Report of Timothy Anderson, M.S., M.B ("First Anderson Rep.") ¶¶ 25, 82, 89-90, 165-74, Jan. 12, 2022; Ex. 23, Deposition of Timothy Anderson ("Anderson 2022 Dep.") 218:14-219:8; 221:20-:222:13; 237:24-239:2; 245:2-247:19; 433:16-437:12, Mar. 9, 2022; Ex. 24, Report of Roger Lea Williams, M.D. ("Williams Rep.") ¶¶ 29, 39, 86-91, Jan. 12, 2022; Ex. 25, Deposition of Roger Lea Williams ("Williams 2022 Dep.") 47:5-48:20; 209:8-210:13, Feb. 17, 2022.)

19. The Teva Defendants' Quality Control and Standard Operating Procedures at all relevant times were consistent with cGMP requirements. (Ex. 22, First Anderson Rep. ¶¶ 22-24, 56-57, 102-03; Ex. 23, Anderson 2022 Dep. 77:19-77:18; 98:19-99:17; 256:11-258:2; 276:3-281:16; 309:3-7; 426:5-429:23.)

20. The Teva Defendants tested all incoming ZHP API. (Ex. 26, Liability Deposition of Steven W. Baertschi ("Baertschi Liab. Dep.") 134:18-135:11, 306:12-307:13, Jan. 26, 2023.)

21. The Teva Defendants tested their at-issue VCDs in accordance with compendial requirements, approved regulatory specifications, and industry standards, including performing all testing required by the USP Monograph and ANDA, as well as all testing required and contemplated by genotoxic / mutagenic impurity guidances, including ICH M7, and performing appropriate evaluation and testing of residual solvents. (Ex. 27, Deposition of Steven W. Baertschi ("Baertschi Dep.") 82:1-17, 144:21-146:2-19, 327:4-15, Mar. 23, 2022; Ex. 28, Report of Steven W. Baertschi, Ph.D. ¶¶ 12-14, 36-38, Jan. 12, 2022; Ex. 29, Report of Steven W. Baertschi, Ph.D. ("Baertschi Liab. Rep.") ¶¶ 15-16, Dec. 19, 2022.)

22. When ZHP's manufacturing process for its API changed, the Teva Defendants performed a risk assessment to assess the potential for the formation of additional or different impurities as a result of the process change. (Ex. 26, Baertschi Liab. Dep. 268:21-270:6.)

23. The Teva Defendants' Annual Products Reviews, which Plaintiffs' own expert described as "one of the best, in my opinion, summary documents that points to all the records that [the FDA] want[s] to see," reflected that Teva performed its own testing and did not copy data from ZHP's certificates of analysis. (Ex. 30, Liability Deposition of Philip Russ ("Russ Liab. Dep.") 142:2-4, 144:2-3, 233:17-234:21, Jan. 5, 2023.)

24. The Teva Defendants were not denied inspection of ZHP's facilities, did not ignore unfavorable information, and did not prioritize price ahead of patient safety. (*See* Ex. 22, First Anderson Rep. ¶¶ 111-143; Ex. 23, Anderson 2022 Dep. 327:18-328:20; 405:12-408:1; Ex. 31, Deposition of Jens Nassall, 59:15-62:4, June 30, 2021.)

25. In the years leading up to the valsartan recall, Torrent's Indrad facility regularly passed FDA inspections. (*See* Ex. 32, Report of Akhilesh Nagaich, Ph.D. ("Nagaich Rep.") ¶ 80, Dec. 22, 2022; Ex. 33, FDA Compliance Dashboard, "Inspection Classification Database," Torrent Pharmaceuticals Ltd.)

26. Torrent conducted independent testing of every batch of API that it received from ZHP. (Ex. 32, Nagaich Rep. ¶¶ 16-19 ; Ex. 30, Russ Liab. Dep. 246:1-247:2.)

27. Torrent used a robust supplier qualification program to conduct risk assessments for its API supplier, ZHP. (Ex. 32, Nagaich Rep. ¶¶ 16-19.)

28. Torrent fully complied with cGMP regulations. (*Id*.)

29. Although the FDA issued a Warning Letter in October 2019 following an inspection of the Indrad facility, none of the observations listed in the Warning Letter pertained to API testing, or trace impurities in Torrent's products. (Warning Letter, Torrent Pharmaceuticals Limited, MARCS-CMS 585255 — OCTOBER 08, 2019," https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warningletters/torrent-pharmaceuticals-limited-585255-10082019.)

30. Torrent's Quality Control and Standard Operating Procedures at all relevant times were consistent with cGMP requirements. (Ex. 32, Nagiach Rep. ¶ 86.) Torrent's reliance on third-party auditors to audit its API suppliers was also consistent with cGMP requirements. (*Id.* ¶¶ 17-18, 72.)

31. Torrent tested its VCDs in accordance with compendial requirements, approved regulatory specifications, and industry standards. (*Id.* ¶¶ 85-87, 90; Ex. 34, Deposition of Akhilish Nagaich ("Nagaich Dep.") 164:22-165:2, Feb. 9, 2023; Ex. 35, Deposition of Sushil Jaiswal Vol. II 503:1-4, June 5, 2021.) Because the compendial standards did not include any specifications for nitrosamines, nothing in that testing suggested the presence of nitrosamines. (Ex. 34, Nagaich Dep. 223:16-224:1.)

32. The undisputed record reflects that the potential cost to Torrent was not the primary factor driving its recall decisions. (*See* Ex. 36, Deposition of Dawn Chitty ("Chitty Dep.") 231:4-11, May 13, 2021.)

33. As one of Torrent's corporate representatives explained, financial implications "ha[ve] no impact on the decision making process. Your decision is always based upon the science." (Ex. 37, Deposition of Sushil Jaiswal Vol. I ("Jaiswal Dep. Vol. I") 259:19-22, June 4, 2021.)

D. Discovery Of The Impurity In Valsartan API.

34. On May 21, 2018, Novartis AG ("Novartis"), a prospective customer of ZHP, contacted ZHP regarding several unknown peaks—i.e., unidentified substances, that it had discovered when testing samples of ZHP's API using gas chromatography flame ionization detection, also known as GC-FID. (*See* Ex. 38, ZHP02172439; Ex. 39, ZHP02172447, at 465-471.) The two companies exchanged a series of emails as they worked together to investigate the unknown peaks. (*See* Ex. 40, ZHP00389304.)

35. In the course of the investigation, Novartis suggested that a third-party laboratory—Solvias AG ("Solvias")—conduct an analysis to identify the peaks using gas chromatography-mass spectrometry ("GC-MS") technology. (Ex. 41, ZHP00400281 at 281-298.) On June 11, 2018, Novartis informed ZHP via email that

Solvias had identified one of the unknown peaks as NDMA, a type of nitrosamine. (Ex. 42, ZHP01875818 at 822.)

36. Following Solvias's identification of NDMA in ZHP's API, ZHP immediately developed a quantitative analytical method for identifying NDMA, confirmed the presence of NDMA, and notified the FDA of its findings through its U.S. subsidiary, Prinston. (Ex. 43, ZHP00002079 at 2080.)

37. After notifying the FDA of the finding of NDMA, ZHP and Prinston continued to work closely with the agency to determine the appropriate path forward and identify the root cause of the impurity. (Ex. 44, PRINSTON00074186 at 74209-14 (detailing root cause for NDMA formation).)

38. On July 13, 2018, shortly after confirming the presence of NDMA in certain samples of valsartan API, ZHP initiated a voluntary Class II recall of finished-dose VCDs containing its valsartan API in conjunction with the FDA. ZHP was the first manufacturer to provide data regarding the discovery of NDMA to the FDA. (*See* Ex. 1, July 13 FDA News Release; Ex. 2, SOLCO00000173.)

39. The Teva Defendants first learned that there was a previously unknown impurity in ZHP's API when ZHP informed them of the issue on June 20, 2018. (*See* Ex. 45, Deposition of Daniel Barreto Vol. I 247:11-252:17, Apr. 14, 2021; Ex. 46, TEVA-MDL2875-00565758 at -5763.)

40. Neither the Teva Defendants' testing of their VCD nor their audits of ZHP and other suppliers provided evidence to suggest NDMA would be present in the API purchased from ZHP. (Ex. 23, Anderson 2022 Dep. 432:23-436:19; Ex. 27, Baertschi Dep. 325:6-327:15.)

41. Upon learning of the presence of impurities in ZHP's valsartan API, the Teva Defendants initiated a voluntary recall of their corresponding VCDs on July 16, 2018. (Ex. 22, First Anderson Rep. ¶¶ 74-75, 100; Ex. 47; TEVA-MDL2875-00640941; Ex. 48, TEVA-MDL2875-00063796.)

42. Torrent received an initial notice from ZHP regarding potential impurities in the Valsartan API manufactured by ZHP, and first learned of the presence of an unknown impurity, which was later identified as NDMA, in ZHP's Valsartan API on June 20, 2018. (Ex. 49, TORRENT-MDL2875-00159677; Ex. 50, TORRENT-MDL-2875-00523108.) While it was not immediately clear whether all Valsartan API was affected, Torrent took immediate steps to quarantine the product. (Ex. 51, TORRENT-MDL2875-00099932.)

43. ZHP initially believed that the impurity was not present in the valsartan API it supplied to Torrent due to the specifics of the manufacturing process used to manufacture that API. (*See* Ex. 52, ZHP00004352, at 4386-87.) Specifically, initial information from ZHP shared with Torrent indicated that the Valsartan API ZHP provided to Torrent was manufactured using Trimethylamine Hydrochloride

("TEA") as the reagent (the "TEA Process"), and was not affected by the impurity issue. (*See* Ex. 53, TORRENT-MDL2875-00523106.) Instead, the information indicated that only Valsartan API manufactured using Zinc Chloride as the reagent (the "Zinc Chloride Process") was affected. (*Id*.) Torrent only purchased Valsartan API manufactured using the TEA Process, and did not purchase any Valsartan API manufactured using the Zinc Chloride process. (Ex. 37, Jaiswal Dep. Vol. I 67:21-68:7, June 4, 2021.) Thus, the initial information ZHP provided to Torrent indicated that the ZHP API used by Torrent in manufacturing its VCDs was not affected by the impurity. (*See* Ex. 53, TORRENT-MDL2875-00523106.)

44. On June 26, 2018, Torrent received another notice from ZHP, confirming that the impurity issue did not implicate batches of API manufactured using the TEA Process (D5191). (*Id*.)

45. On August 3, 2018, Torrent received notice from ZHP for the first time that trace amounts of NDMA were detected in Valsartan API manufactured using the TEA Process (C5069). (Ex. 32, Nagaich Rep. ¶ 105; Ex. 36, Chitty Dep. 287:13-288:9; Ex. 54, TORRENT-MDL2875-00143643.) Torrent had no reason to believe there were nitrosamine impurities in the API used to manufacture its VCDs prior to receiving this notification. (*See* Ex. 54, TORRENT-MDL2875-00143643.)

46. Torrent initiated a voluntary recall of its finished-dose VCDs using ZHP's API by issuing recall notices to customers beginning on August 17, 2018. (Ex. 32, Nagaich Rep. ¶ 105; Ex. 55, TORRENT-MDL2875-00004228.)

47. During a teleconference with the European Directorate for the Quality of Medicines & HealthCare ("EDQM") and other European Union authorities on August 07, 2018, ZHP "was asked if there was the possibility that N-Nitrosodiethylamin[e] ('NDEA')," a different nitrosamine, could potentially also be present in ZHP's API. (Ex. 56, ZHP00009256, at 9263.) "[ZHP] immediately initiated the development of [an] analytical method for NDEA." (*Id.*)

48. On August 29, 2018, batches of valsartan API were tested using this method, and the data obtained indicated the presence of trace amounts of NDEA in batches of ZHP's valsartan API. (*Id.*)

49. ZHP informed the EDQM and the FDA of these findings, and the FDA shared them with the public on September 13, 2018. (Ex. 57, FDA News Release, Sept. 13, 2018 "FDA provides update on its ongoing investigation into valsartan products; and reports on the finding of an additional impurity identified in one firm's already recalled products".) The FDA stated that its own "testing show[ed] that not all products made using ZHP valsartan API contain[ed] the NDEA impurity." (*Id.*)

E. Causes Of The Impurities In Valsartan API And VCDs.

50. ZHP's 2018 investigation regarding the origins of the NDMA and NDEA identified in valsartan API is summarized in Deviation Investigation Report Nos. DC DC_E-18001 ("the Preliminary DIR") and DC_E-18003 ("Final DIR"). (*See generally* Ex. 52, ZHP00004352, at 4363-4471; Ex. 56, ZHP00009256.)

51. In the Final DIR, ZHP noted that the "presence of trace amount[s] of NDMA in the final [v]alsartan API requires the convergence of the following three factors . . . i) presence of dimethylamine [('DMA')] in the manufacturing process . . . ii) presence of nitrous acid in the manufacturing process . . . and; iii) [t]he possibility of direct contact between secondary amines [(i.e., DMA)] and nitrite in the presence of the target product [(i.e., valsartan)]." (Ex. 56, ZHP00009256 at 9269-70.)

52. ZHP explained in the Final DIR that "[t]he presence of trace amount[s] of NDEA in the final Valsartan drug substance requires the convergence of the following three factors: . . . [i)] [p]resence of diethylamine [('DEA')] in the manufacturing process . . . [ii)] [p]resence of nitrous acid in the manufacturing process . . . [iii)] [p]ossibility of direct contact between secondary amines [i.e. NDEA] and nitrite in the presence of the target product." (*Id.* at 9313.)

53. Plaintiffs' expert, Dr. Ramin Najafi, has testified—consistent with ZHP's findings in the Final DIR—that the nitrosamine NDMA cannot form without

the presence of the secondary amine DMA, and that the nitrosamine NDEA cannot form without the presence of the secondary amine DEA. (Ex. 58, Deposition of Ron Najafi Vol. I ("Najafi 2023 Dep. Vol. I"), 193:21, Jan. 18, 2023 ("To form NDMA, you need dimethylamine."); *id.* 193:22 ("To form NDEA, you need diethylamine.").)

54. ZHP's investigation into the root causes of how NDEA and NDMA came to be present in its valsartan API focused on identifying whether and how DMA and DEA had been introduced into the processes that ZHP used to manufacture its valsartan API during the proposed class period, and whether that DMA and DEA was exposed to nitrous acid in such a way that it was possible for NDMA and/or NDEA to form. (*See*, *e.g.*, Ex. 56, ZHP00009256 at 9277, 9335.)

55. ZHP determined that "the ultimate reason for the presence of NDEA in Valsartan API (TEA [with quenching] process) [was] due to the process change in which triethylamine (TEA) was introduced as a catalyst and its impurity/degradant, diethylamine, unexpectedly react[ed] with nitrous acid during the subsequent quenching step in the presence of the product of that step." (*Id.* at 9482.)

56. ZHP also concluded that NDMA was able to form in its valsartan API because the DMF solvent used in the Zinc Chloride process had "degraded into dimethylamine, [which] react[ed] with nitrous acid (formed by sodium nitrite and

hydrochloric acid) during the next quenching reaction, and [formed] NDMA." (*Id.* at 9323.)

F. The Formation Of NDMA And NDEA In Valsartan API Was Unexpected.

57. A limited number of publications have suggested (in passing) that DMF solvent could decompose at its boiling point into DMA, a necessary component of NDMA. (*See* Ex. 59, Report of Stephen S. Hecht, Ph.D. ("2021 Hecht Rep.") at 18, July 6, 2021; Ex. 60, Report of Ramin (Ron) Najafi, Ph.D. ("Najafi Rep.") at 26, Oct. 31, 2022 (citing *Purification of Laboratory Chemicals, Armarego, WLF (4th Edition 1996, 6th Edition 2009*) ("DMF decomposes slightly at its normal [boiling point] (153C) to give small amounts of dimethylamine and CO.").)

58. Both Dr. Najafi and Dr. Hecht conceded that ZHP's manufacturing processes never reached the temperature necessary for DMF to boil. (*See* Ex. 58, Najafi 2023 Dep. Vol. I 206:11-19; Ex. 61, Deposition of Stephen S. Hecht, Ph.D. ("Hecht Dep.") 218:7-23, Jan. 13, 2023.)

59. Dr. Najafi was not aware of this textbook until his retention for this litigation (*see* Ex. 58, Najafi 2023 Dep. Vol. I 203:2-4), while Dr. Hecht does not know if the isolated statements regarding DMF decomposition are common knowledge even today (*see* Ex. 61, Hecht Dep. 211:8-11, 212:5-12). Dr. Najafi also testified that, despite having a Ph.D. in chemistry and operating his own laboratory,

he first became aware of the possibility that TEA exposed to sodium nitrite could ultimately form NDEA in connection with this litigation. (*See* Ex. 58, Najafi 2023 Dep. Vol. I 192:18-193:7; *see also id.* 193:8-15 (Dr. Najafi answering "yes" when asked if he learned of the reaction by which TEA could form NDEA "through [his] investigation in connection with this litigation").) Similarly, Dr. Hecht was unable to identify any scientific literature that documented a reaction between TEA and sodium nitrite leading to the creation of NDEA prior to or during the time that the TEA with quenching process was being used to manufacture ZHP's API. (*See generally* Ex. 59, 2021 Hecht Rep.; Ex. 62, Report of Stephen S. Hecht, Ph.D. ("2022 Hecht Rep."), Oct. 31, 2022.) Indeed, Dr. Hecht has acknowledged that it was historically understood that "a tertiary amine," such as TEA "would not react" with sodium nitrite to form a nitrosamine. (*See* Ex. 59, 2021 Hecht Rep. at 18.)

60. Dr. Najafi also advanced a theory that the TEA used by ZHP itself ***may*** have contained DEA. (*See* Ex. 58, Najafi 2023 Dep. Vol. I 193:22-24.) But none of Plaintiffs' experts points to any evidence that ZHP's TEA contained DEA; instead, they cite a single record discussing it as a potential issue raised after the recall, underscoring the lack of evidence that ZHP could have known NDEA formation occurred during the class period. (*See* Ex. 62, 2022 Hecht Rep. at 10; *see also* Ex. 63, PRINSTON00075797-5977.)

61. In its first announcement regarding the Valsartan recall in July 2018, the FDA expressly stated that "the presence of NDMA was unexpected and [was] thought to be related to changes in the way the active substance was manufactured." (Ex. 1, July 13 FDA News Release at 1.)

62. In a statement issued by Dr. Scott Gottlieb, the FDA Commissioner, on August 30, 2018, the agency reiterated this message, stating: "Before [the FDA] undertook [an] analysis [following the discovery of NDMA in ZHP's valsartan API], neither regulators nor industry fully understood how NDMA could form during this process." (Ex. 64, FDA Statement, Aug. 30, 2018 "FDA Statement on FDA's ongoing investigation into valsartan impurities and recalls and an update on FDA's current findings" ("August 2018 Gottlieb Statement") at 4.)

63. Dr. Gottlieb also noted that "NDMA's properties make it difficult to find," and that "[b]ecause it was not anticipated that NDMA would occur at these levels in the manufacturing of the valsartan API, manufacturers would not have been testing for it." (*Id.*)

64. In a subsequent statement issued by Dr. Gottlieb on January 25, 2019, the FDA again reiterated that "[o]ne challenge [the FDA] faced is that NDMA's properties make it hard to detect in standard laboratory testing – the kind of testing results that are reviewed during a surveillance inspection." (Ex. 65, FDA Statement, Jan. 25, 2019 "FDA Statement on the FDA's ongoing investigation into valsartan

and ARB class impurities and the agency's steps to address the root causes of the safety issues" ("FDA Statement, Jan. 25, 2019") at 3.)

65. The FDA also explained that "it generally needs to be recognized that there's a risk of an impurity occurring as a result of a manufacturing process to know the impurity should be tested for." (*Id.*)

66. Dr. Najafi asserts that a 2017 email from ZHP employee Jinsheng Lin shows that ZHP did have knowledge of the potential for NDMA or NDEA resulting from its manufacturing processes, but that email is not even about valsartan API—the product in question. (*See* Ex. 60, Najafi Rep. at 30-31.) Rather, as explained by Dr. Fengtian Xue, a Professor of Chemistry and native Chinese speaker, Mr. Lin's email addresses a hypothetical nitrosated impurity in the lab-scale production of Irbesartan, a different drug molecule than valsartan API. (*See* Ex. 66, Report of Dr. Fengtian Xue at 55, Dec. 22, 2022.)

G. The FDA And Industry Did Not Have Standards Or Testing Methods For NDMA Or NDEA Prior To The Recall Of The VCDs At Issue.

67. Analyzing low-level impurities such as the NDMA and NDEA found in VCDs is extremely difficult and requires specialized equipment, analytical testing methods and expertise. Drug manufacturers could not test for every conceivable impurity without knowing the structure of the impurity, and it is particularly difficult to detect and quantify unknown impurities at such low levels as the NDMA and

NDEA impurities found in VCDs because the peaks were so low that they would not have stood out as unknown to flag and investigate. (*See* Ex. 29, Baertschi Liab. Rep. ¶¶ 12-13; Ex. 26, Baertschi Liab. Dep. 139:18-20, 150:1-19, 242:16-21, 251:14-252:1, 272:20-273:11, 289:23-290:8, 291:11-24, 292:9-293:7.)

68. At the time the recalled VCDs were approved by the FDA, and continuing through the time of the recalls beginning in July 2018, there was no specification for nitrosamine impurities in VCDs. Specification testing for VCDs prior to 2018 did not include testing capable of detecting NDMA at the levels at issue here. (Ex. 27, Baertschi Dep. 327:4-15; Ex. 12, Afnan Rep. ¶ 72 ("In 2012, the USP standards only provided explicit tests for, and limits regarding, three specific compounds for Valsartan.").)

69. At the time the VCDs at issue were approved by the FDA, and continuing through the time of the recalls beginning in July 2018, there were also no validated or industry-standard methods or practices to test for the presence or absence of NDMA or NDEA in VCDs. (Ex. 12, Afnan Rep. ¶ 182 ("GC-MS was not validated or shown to be suitable for the detection of NDMA/NDEA prior to May 2018."); *see also* FDA, Combined N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay by GC/MS-Headspace , https://www.fda.gov/media/117843/download (FDA's Office of Testing and Research reporting that it "ha[d] developed a gas chromatography-mass

spectrometry (GC/MS) headspace method to detect the presence of NDMA and NDEA in valsartan drug substances" in late August, 2018).)

70. The levels of all unknown impurities in valsartan medications, including the NDMA and NDEA impurities that were discovered, were within the limits of the specifications approved by the FDA for unknown impurities at all times that the VCDs at issue were available to patients. (Ex. 29, Baertschi Liab. Rep. ¶ 14; Ex. 26 Baertschi Liab. Dep. 284:21-286:20; 315:20-317:16.)

71. Plaintiffs' organic chemistry expert, Dr. Stephen Hecht, stated that the TPP Trial Defendants "would not have identified NDMA in the chromatograms unless they were specifically looking for it, because the peaks would be too small." (Ex. 59, 2021 Hecht Rep. at 20; Ex. 61, Hecht Dep. 129:17-130:14, 203:15-24.)

72. At the time the VCDs at issue were approved by the FDA, and continuing through the time of the recalls beginning in July 2018, the United States Pharmacopeia ("USP") did not contain any standard relating to permissible or impermissible quantities of NDMA or NDEA in VCDs. (Ex. 12, Afnan Rep. ¶ 211 (noting "[t]he bioequivalence standard does not address inactive ingredients or impurities"); *see also* 21 C.F.R. § 314.3(b) (Bioequivalence).)

73. Prior to July 2018, there was no FDA standard, testing methodology, or other regulatory or industry standards or requirements pertaining to limits of NDMA in VCDs. (*See* Ex. 12, Afnan Rep. ¶¶ 72, 181-183; *see also* ICH Q3A (R2) at 3-5,

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-3-r2-impurities-new-drug-substances-step-5_en.pdf; FDA, Combined N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay by GC/MS-Headspace , https://www.fda.gov/media/117843/download; Ex. 67, USP 35, Official Monographs (2012), at 4997-98; Ex. 68, USP 35, Chemical Tests (2012), <467> Residual Solvents, at 185, 189-92.)

74. The FDA did not develop and issue any method for the detection of NDMA or NDEA in VCDs until October 11, 2018, after the valsartan recalls. (https://www.fda.gov/media/115965/download#:~:text=Accurately%20weigh%20500%20mg%20of,impurity%20in%20the%20drug%20substance.)

75. The FDA did not publish a table of interim acceptable intake limits for nitrosamines, including NDMA and NDEA, in VCDs, until December 19, 2018, and did not confirm those limits until February 2021. (*See* Ex. 69, FDA Recall Press Releases at 13 ("12/19/2018 UPDATE – FDA presents interim limits of nitrosamines in currently marketed ARBs"); Ex. 70, FDA Guidance for Industry, "Control of Nitrosamine Impurities in Human Drugs," February 2021.)

76. USP first published a chapter on nitrosamine impurities in September 2020. *See* https://www.usp.org/sites/default/files/usp/document/stakeholder-forum/pnp/highlights-of-1469-nitrosamine-impurities.pdf.

H. The VCDs At Issue Were Effective Anti-Hypertension Medications With Trace Impurity Levels.

77. The FDA stated in August 2018 that "the levels of NDMA in ZHP's valsartan API" constituted "trace amounts." (Ex. 64, August 2018 Gottlieb Statement at 2.)

78. In the same statement, the FDA "estimated that if 8,000 people took the highest valsartan dose (320 mg) from NDMA-affected medicines daily for four years (the amount of time we believed the affected products had been on the U.S. market), there may be one additional case of cancer over the lifetimes of these 8,000 people beyond the average cancer rate among Americans. This estimate represented the highest possible level of NDMA exposure. It was a measure of the risk under the most extreme circumstances. Most patients who were exposed to the impurity through the use of valsartan received less exposure than this worst-case scenario." (*Id*. at 3.) Similarly, the FDA stated that it "estimate[s] that if 18,000 people took valsartan at the highest dose (320 mg) containing NDEA from recalled batches daily for four years, there may be one additional case of cancer over the lifetime of these 18,000 people." (Ex. 71, FDA, Laboratory Analysis of Valsartan Products.) Indeed, in January 2019, the FDA again reiterated that the "risk to individual patients remains very small." (Ex. 65, FDA Statement, Jan. 25, 2019.)

79. There is no evidence that any VCD subject to the recall did not serve its intended purpose of providing effective antihypertension treatment. Plaintiffs' expert Dr. Rena Conti admitted she could not identify any scientific evidence indicating that, between 2012 and 2018, generic valsartan available on the market was not effective in treating hypertension. (Ex. 72, Deposition of Rena Conti, Ph.D. 138:25-139:5, Feb. 10, 2022.)

80. Plaintiffs' expert Dr. Najafi was unable to dispute that "the defendant's valsartan products . . . lower[ed] blood pressure in adults and children" who used the products. (Ex. 73, 2022 Deposition of Ron Najafi ("Najafi 2022 Dep.") 192:24-193:10, Feb. 3, 2022.)

81. Given the efficacy and important medical benefits provided by VCDs, the FDA stated in its July 13 News Release about the recall that individuals should not stop taking the drug immediately. According to the FDA: "[b]ecause valsartan is used in medicines to treat serious medical conditions, patients taking the recalled valsartan-containing medicines should continue taking their medicine until they have a replacement product." (Ex. 1, July 13 FDA News Release at 1.)

82. In a statement from Dr. Gottlieb dated April 4, 2019, the FDA stated that "[t]he risk associated with abruptly discontinuing the use of these important medicines far outweighs the low risk that our scientists estimate to be associated with continuing the medicine until the patient's doctor or pharmacist provides a safe

replacement or a different treatment option." (Ex. 74, FDA Statement, Apr. 4, 2019, "FDA Statement on the agency's list of known nitrosamine-free valsartan and ARB class medicines, as part of agency's ongoing efforts to resolve ongoing safety issue" at 3.)

I. The TPP Trial Defendants Did Not Make Or Violate Any Warranties Or Representations Regarding NDMA In Valsartan API Or The At-Issue VCDs

83. The TPP Trial Defendants did not make any warranties or representations on their labels, websites, or anywhere else regarding the presence or absence of NDMA in their respective valsartan API or VCDs prior to the recalls beginning in July 2018. (*See, e.g.*, Ex. 75, Report of Timothy E. Kosty ("Second Kosty Rep.") ¶¶ 67-68, Dec. 19, 2022; *see also* Ex. 76, Deposition of Timothy Kosty ("Kosty Dep.") 113:21-114:15, 140:25-145:4, Feb. 23, 2023.)

84. Neither Emblem nor SummaCare, on whose behalf named Plaintiff MSP has brought suit, received any representations from any TPP Trial Defendant. Tiffanie Mrakovich, the Rule 30(b)(6) representative witness for Summacare, testified that Summacare "does not have any direct relationship with manufacturers" and "we do not have any warranties in place with manufacturers directly." (Ex. 77, Deposition of Tiffanie Mrakovich Vol. I ("Mrakovich Dep. Vol. I") 14:2-14, July 22, 2021.)

85. Margaret Finn, the Rule 30(b)(6) representative witness for Emblem, testified that she did not know whether anyone from Emblem had ever read defendants' website or otherwise had any communications "with any of the defendants in this action regarding valsartan." (Ex. 78, Deposition of Margaret Finn ("Finn Dep.") 278:23-279:2, 279:8-17, July 30, 2021.) She did not know of anyone at Emblem ever going to any Defendant's website or reviewing printed literature regarding VCDs from any Defendant. (*Id*. 279:4-12.) Finn did not know of any express warranties made by any Defendant to Emblem regarding VCDs. (*Id*. 279:18-22.)

86. The levels of all impurities in the VCDs at issue were within the specification limits approved by the FDA via the ANDA. (Ex. 79, Report of Eric Sheinin ("Sheinin Rep.") ¶¶ 97, 100, Jan. 12, 2022; Ex. 29, Baertschi Liab. Rep. ¶ 36; Ex. 26, Baertschi Liab. Dep. 132:4-24; 134:15-135:19; Ex. 30, Russ Liab. Dep. 168:23-169:14, 172:16-24.)

87. The referenced listed drugs ("RLDs") for the various VCDs at issue in this case are "Diovan," "Diovan HCT," "Exforge," and "Exforce HCT," all of which belong to a class of medications known as Angiotensin Receptor Binders ("ARBs")." (Ex. 80, Report of Kali Panagos, Pharm.D., RPH ("Panagos Rep.") ¶¶ 13-14, Nov. 9, 2021.)

88. For an ANDA holder to obtain approval for a generic drug, it must demonstrate to the FDA that its product is pharmaceutically equivalent and bioequivalent to the RLD. (Ex. 24, Williams Rep. ¶¶ 50, 52; Ex. 25, Williams 2022 Dep. 222:23-223:20; Ex. 81, Report of Michael Bottorff, Pharm. D. ("Bottorff Rep.") 25:418-27:463, Jan. 12, 2022; Ex. 82, Deposition of Michael Bottorff, Pharm. D. ("Bottorff Dep.") 39:7-9; 40:9-14; 210:1-4; 247:20-248:21, Feb. 17, 2022; Ex. 32, Nagaich Rep. ¶ 30; *see also* 21 CFR § 314.94(a)(7); 21 U.S.C. § 355(j)(2)(A)(iii-iv).)

89. Pharmaceutical equivalence means, among other things, that the generic drug is the same as the RLD in terms of active ingredient(s), strength, dosage form, and route of administration. (Ex. 24, Williams Rep. ¶ 50; Ex. 81, Bottorff Rep. 25:419-421; Ex. 32, Nagaich Rep. ¶¶ 32, 34; *see also* 21 U.S.C. § 355(j)(2)(A)(iii).)

90. Bioequivalence means the generic product is absorbed into the bloodstream at a similar rate and similar extent as the RLD. (Ex. 24, Williams Rep. ¶ 52; Ex. 25, Williams 2022 Dep. 218:8-16 *see also* Ex. 83, *Bioavailability and Bioequivalence: An FDA Regulatory Overview, Pharmaceutical Research*, Vol. 18, No. 12, December 2001.)

91. When an ANDA product is approved by the FDA as therapeutically equivalent and bioequivalent, it is typically given an AB-rating, allowing it to be

substituted by a pharmacist for the branded drug. (Ex. 24, Williams Rep. ¶ 62; Ex. 25, Williams 2022 Dep. 223:15-20.)

92. The presence of impurities does not implicate pharmaceutical equivalence, bioequivalence, or AB ratings. (Ex. 25, Williams 2022 Dep. 218:8-219:5; Ex. 84, Deposition of Eric Sheinin ("Sheinin Dep.") 215:3-14, 218:21-219:13, Mar. 21, 2022; Ex. 73, Najafi 2022 Dep. 20:9-10; 20:23-21:4.)

93. The FDA allows different impurity profiles in drugs, and changes in impurities do not create different or new drugs. (Ex. 24, Williams Rep. ¶ 118; Ex. 25, Williams 2022 Dep. 218:8-219:5.)

94. The presence of NDMA in generic VCDs did not alter their bioequivalence or clinical efficacy; nor did it have any impact on how the VCDs work—i.e., their pharmacokinetics or pharmacodynamics. (Ex. 81, Bottorff Rep. at 5:101-6:104; Ex. 82, Bottorff Dep. 18:4-6, 82:3-8, 224:15-18, 236:21-237:4, 238:22-239:3.)

J. The TPP Trial Defendants Did Not Sell Adulterated VCDs

95. "Adulteration" is a statutorily defined regulatory determination, and the FDA alone determines whether a product is adulterated. (*See* Food, Drug & Cosmetic Act § 501(a)(2)(B); Ex. 25, Williams 2022 Dep. 198:8-18; Ex. 85, Dep. of Timothy Anderson 292:4-8, Feb. 9, 2023; Ex. 23, Anderson 2022 Dep. 124:9-12; Ex. 86, Deposition of Laura M. Plunkett 343:19-23, 345:3-8, Feb. 10, 2023).

96. The FDA did not find or declare any API used to manufacture VCDs "adulterated" until, at the earliest, November 29, 2018, by which time all medications containing the affected ZHP API had been voluntarily recalled. (Ex. 25, Williams 2022 Dep. 164:3-11, 202:4-15; Ex. 12, Afnan Rep. ¶ 209; *see also* Ex. 91, ZHP00393513.)

97. The FDA did not issue any Warning Letters to put any import hold on Teva's VCDs, did not take any regulatory action with respect to Teva's VCDs in connection with nitrosamine impurities, and did not send any communications to Teva that products sold under its ANDAs were no longer AB-rated to their corresponding RLDs. (Ex. 22, First Anderson Rep. ¶¶ 25, 27, 82, 89-90; Ex. 87, Report of Timothy Anderson, M.S., M.B.A. ("Second Anderson Rep.") ¶¶ 190, 221, Dec. 19, 2022; Ex. 23, Anderson 2022 Dep. 125:13-20, 128:3-18; Ex. 88, Dep. of Roger Williams. 233:19-23, Jan. 31, 2023; Ex. 24, Williams Rep. ¶¶ 29, 39, 86-91; Ex. 89, Report of Roger Lea Williams, M.D. ("Williams Corrected Rep.") ¶¶ 144-45, Dec. 19, 2022, revised Jan. 28, 2023.)

98. At all relevant times prior to each manufacturer's recall, all at-issue VCDs met their compendial and approved Drug Master File and ANDA specifications and their labeling conformed to the RLDs. (Ex. 90, Deposition of Richard Glover Vol. I 84:24-85:7, Mar. 9, 2021; Ex. 79, Sheinin Rep. ¶¶ 39, 102; Ex. 24, Williams Rep. ¶¶ 30, 40-42, 110-13, 124; Ex. 25, Williams 2022 Dep. 205:5-

210:13; Ex. 22, First Anderson Rep. ¶¶ 58-73; Ex. 87, Second Anderson Rep. ¶ 215; Ex. 23, Anderson 2022 Dep. 218:7-220:8; Ex. 32, Nagaich Rep. ¶¶ 85-87, 90; Ex. 7, Osmian Dep. 94:15-95:7.)

99. At all times prior to the recall, all VCDs with ZHP API met compendial and approved Drug Master File and ANDA specifications, and the FDA has never made a final regulatory determination that ZHP's API was adulterated or misbranded. (Ex. 12, Afnan Rep. ¶¶ 194-212; *see also* FDA, *Form 483 Frequently Asked Questions*, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions ("The FDA Form 483 does not constitute a final Agency determination of whether any condition is in violation of the FD&C Act or any of its relevant regulations"); FDA, Regulatory Procedures Manual § 4-1-1, at 4 (June 2022), https://www.fda.gov/media/71878/download ("A Warning Letter is informal and advisory. It communicates the agency's position on a matter, but it does not commit [the] FDA to taking enforcement action. For these reasons, FDA does not consider Warning Letters to be final agency action on which it can be sued."); Ex. 91, ZHP00393513.)

100. The Teva Defendants' at-issue VCDs met all compendial and approved ANDA specifications for the product at all times prior to Teva's voluntary recall, and at no time did the FDA make the regulatory determination that Teva's valsartan

drugs were adulterated. (Ex. 24, Williams Rep. ¶¶ 27, 29-30, 40, 42, 110-13, 124; Ex. 25, Williams 2022 Dep. 63:19-21, 205:5-210:13; Ex. 89, Williams Corrected Rep. ¶¶ 22-23, 144-45; *see* Ex. 30, Russ Liab. Dep. 92:23-95:1 ("A: The determination of a product being adulterated itself is – is not something I am opining on in my report. . . . Q. [Y]ou are not going to give the opinion that any of the product manufactured by Teva was adulterated? A. No, I am not.").)

101. All of Torrent's VCDs met their compendial and approved Drug Master File and ANDA specifications at all relevant times prior to Torrent's voluntary recall. (Ex. 32, Nagaich Rep. ¶¶ 85-87, 90.) Torrent never received notice that the FDA made any regulatory determination that Torrent's VCDs were adulterated.

K. MSP And The TPP Class Members Lack Privity With The TPP Trial Defendants

102. MSP is not a TPP and has never been a plan sponsor. (Ex. 92, Deposition of Jorge A. Lopez ("Lopez Dep.") 24:6-25:5, Apr. 29, 2021.)

103. MSP's affiliate entity, MSP Recovery, LLC, stores, reviews and analyzes claims data (Ex. 92, Lopez Dep. 132:6-24), and its affiliated law firm sues over them (*id*. 134:6-135:8).

104. TPPs are just one part of the intricate web of manufacturers, wholesalers, pharmacies, third-party administrators ("TPAs"), insurance providers, Administrative Services Only providers ("ASOs"), federal and state governments,

and pharmacy benefit managers ("PBMs") that make up the pharmaceutical supply chain and benefits flow, all of which may (or may not) be involved in any given prescription payment. (Ex. 93, Report of Timothy E. Kosty ("First Kosty Rep.") ¶¶ 39-41, Jan. 12, 2022; *see also* Government Accountability Office, *Generic Drugs Under Medicare*, at 7, https://www.gao.gov/assets/gao-16-706.pdf (August 2016).)

105. MSP's assignors, including Emblem and Summacare, provide "fully insured" plans to some of their clients, as well as Medicare Advantage plans directly to consumers. (*See* Ex. 93, First Kosty Rep. ¶ 47; *see also* EmblemHealth, *Why EmblemHealth?*, https://www.emblemhealth.com/employers/about; Ex. 78, Finn Dep. 32:4-33:1; Ex. 77, Mrakovich Dep. Vol. I 24:23-25:18.)

106. Emblem also offers a Medicaid Managed Care plan to low-income persons. (*See* Ex. 78, Finn Dep. 32:4-33:1.)

107. MSP and the TPP class members have no direct contractual relationship with the TPP Trial Defendants. TPPs generally do not even contract directly with pharmacies to pay for prescriptions. Rather, TPPs contract with one or more intermediaries. (*See* Ex. 93, First Kosty Rep. ¶ 39 Fig. 1; *see also* Government Accountability Office, *Generic Drugs Under Medicare*, at 7, https://www.gao.gov/assets/gao-16-706.pdf (August 2016).)

108. SummaCare's corporate representative testified that SummaCare does "not have any warranties in place with manufacturers directly." (Ex. 77, Mrakovich

Dep. Vol. I 14:11-14.) Similarly, Emblem's corporate representative replied "I don't know" when asked if it was Emblem's "position that any defendants in this action made express warranties to [it] regarding valsartan." (Ex. 78, Finn Dep. 279:18-22.)

109. PBMs, and possibly other entities, were involved in insured pharmaceutical transactions at issue in this case. (*See* Ex. 93, First Kosty Rep. ¶ 39 Fig. 1; *see also* Government Accountability Office, *Generic Drugs Under Medicare*, at 7, https://www.gao.gov/assets/gao-16-706.pdf (August 2016).)

110. The PBM pays for the drug directly and then seeks repayment from its client. In some cases, the client is a TPP and the PBM bills the TPP directly. In other cases, a TPP will contract with a TPA or ASO provider. (*See* Ex. 93, First Kosty Rep. ¶¶ 39-40; *see also see also* Government Accountability Office, *Generic Drugs Under Medicare*, at 7, https://www.gao.gov/assets/gao-16-706.pdf (August 2016); Ex. 94, Declaration of Laura Craft, ¶ 68, Nov. 10, 2021.)

111. About half of self-funded employers that provide health coverage to employees contract with a TPA instead of directly with a PBM. In those cases, the TPA or ASO pays the PBM, and then bills its client (often, but not always, the TPP). (Ex. 93, First Kosty Rep. ¶ 60; Ex. 95, Dep. of Laura R. Craft ("Craft Dep.") 147:19-149:2, Feb. 18, 2022.) SummaCare, for example, receives an invoice from its PBM for all claims that the PBM paid to the pharmacy on behalf of SummaCare's members. For self-funded plans, SummaCare then directly bills its client to pay those

costs. For fully-insured plans, SummaCare pays the invoice to its PBM. *See* Ex. 96, Deposition of Tiffanie Mrakovich Vol. II 14:25-15:10, Aug. 31, 2021.

L. MSP And The TPP Class Members Did Not Provide Pre-Suit Notice Of Their Claims To Any Of The TPP Trial Defendants

112. There is no evidence in the record that MSP, its assignors, or any of the TPP Class members ever provided pre-suit notice of any of their claims to any of the TPP Trial Defendants prior to filing suit. (*See, e.g.*, Ex. 78, Finn Dep. 279:24-280:2.)

M. MSP And The TPP Class Members Rely On Their PBMs' And P&T Committees' Formulary Placement Of VCDs

113. The extent to which a TPP will cover the cost of a generic medication, such as a VCD, is governed by its formulary, a continually updated list of medications approved for reimbursement. Approved medications are sorted into tiers, structured to encourage members to use the most cost-effective generic drugs available. (Ex. 93, First Kosty Rep. ¶ 76-77; *see also* Ex. 77, Mrakovich Dep. Vol. I 42:22-5, 69:22-70:17.)

114. Pharmacy and Therapeutics Committees ("P&T Committees") evaluate medications for inclusion on formularies. (Ex. 93, First Kosty Rep. ¶ 65; Ex. 75, Second Kosty Rep. ¶¶ 51-52; Ex. 97, American Society of Health-System Pharmacists, *ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System, American Journal of Health-System Pharmacy*, at 907 (May 15, 2021); AMCP, *Formulary Management*, https://www.amcp.org/about/managed-

care-pharmacy-101/concepts-managed-care-pharmacy/formulary-management (July 18, 2019).)

115. Most P&T Committees are associated with PBMs or health insurance organizations, but a TPP could also have its own P&T Committee. (*See* Ex. 80, Panagos Rep. ¶ 22 & n.2.)

116. Both Emblem and Summacare have their own P&T Committees. (Ex. 77, Mrakovich Dep. Vol. I 54:7-55-7; 78:24-79:1; Ex. 78, Finn Dep. 78:24-79:1.)

117. TPPs use formularies and work with their PBMs to determine, among other things, whether to cover specific drugs or classes of drugs and how to share costs between patients and the TPPs. (Ex. 93, First Kosty Rep. ¶ 63.) One Summacare formulary contained 50 alternatives to treatment with a VCD. (Ex. 98, MSP-SUMMACARE-000162-274.)

118. In 2012, the USP standards only provided explicit tests for, and limits regarding, three specific compounds for Valsartan: USP Valsartan Related Compound A (C24H29N5O3) ("Impurity A"); USP Valsartan Related Compound B (C23H27N5O3) ("Impurity B"); and USP Valsartan Related Compound C (C31H35 N5O) ("Impurity C"). (Ex. 12, Afnan Rep. ¶ 72; *see also* Ex. 67, USP 35, Official Monographs (2012), at 4997-98.)

119. TPPs do not rely on the Orange Book for decisions to reimburse members' claims. P&T Committees merely use the Orange Book to determine

therapeutic equivalence rating for generic drugs, and TPPs typically do not use the Orange Book at all. (Ex. 75, Second Kosty Rep. ¶¶ 47, 58, 60; *see also* Ex. 76, Kosty Dep. 87:11-20, 98:17-99:8, 100:11-19, 106:4-15.)

120. P&T Committees do not consider generic medications from individual manufacturers in their decision-making. (Ex. 75, Second Kosty Rep. ¶ 58.)

121. P&T Committees do not view a listing in the Orange Book as a manufacturer's "assurance" or warranty. Inclusion of products in the Orange Book is expressly independent of any recalls or current regulatory action being taken with respect to a drug product. (Ex. 75, Second Kosty Rep. ¶¶ 48, 62; Ex. 76, Kosty Dep. 90:7-91:22 *see also* FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations*, at xii (2023) https://www.fda.gov/media/71474/download.)

122. P&T committees rely on a wide range of documents and sources to develop formularies. These documents and sources include medical and clinical evidence from the literature, relevant patient utilization and experience, economic data, provider recommendations, FDA-approved package inserts, the product label, published data from clinical trials, and relevant patient experiences. (Ex. 75, Second Kosty Rep. ¶ 59; *see also, e.g.*, Ex. 99, AMCP, *Formularies* at 2, June 24, 2019 (recommending that P&T committees "review and evaluate the medical and clinical evidence from the literature, relevant patient utilization and experience, economic data, and provider recommendations"); Express Scripts, *White Paper: Formulary*

Development at Express Scripts (Dec. 2020), https://express-scripts.com/aboutus/formularyinformation/development/formulary Development.pdf (explaining how Express Scripts develops formularies).)

123. SummaCare's representative could not identify any instance in which SummaCare was exposed to any alleged representation by any TPP Trial Defendant, much less one that was brought to the attention of the PBM that made the ultimate decision to "include or exclude [a drug] from [its] formulary." (Ex. 77, Mrakovich Dep. Vol. I 44:22-25, 49:21-50:5, 53:16-21, 55:1-7.)

124. Emblem's corporate representative was unaware of whether anyone at Emblem ever viewed Defendants' websites or VCD-related literature or ever communicated with Defendants about the medications, and she did not notice any change to any Emblem formulary even after the Valsartan recall. (Ex. 78, Finn Dep. 176:2-9, 278:23-279:22.)

N. The Value Of The Recalled VCDs

125. The presence of NDMA impurities did not impact the efficacy of the VCDs at issue at all, and the VCDs provided the same therapeutic benefit as VCDs that did not contain NDMA impurities. (Ex. 82, Bottorff Dep. 18:4-6, 82:3-8, 224:15-18, 236:21-237:4, 238:22-239:3; Ex. 100, Report of John Flack, M.D., M.P.H. at 9-14, Dec. 19, 2022; Ex. 101, Deposition of John Flack 15:1-10, 52:18-53:7, 60:4-61:5, 63:22-64:5, 66:10-67:10, Feb. 1, 2023; *see also* § G, *supra*.)

126. At the "point of sale," Defendants' VCDs were FDA-approved and were legal to market, purchase, and sell at the time the TPPs paid for them. (*Id*.)

127. MSP and the TPP Class members have not presented evidence that they incurred any direct, out-of-pocket costs associated with the recalls of the VCDs at issue. (*See, e.g.*, Ex. 77, Mrakovich Dep. Vol. I 181:16-19 (answering "I do not have that number" when asked to provide "the approximate total costs incurred by SummaCare as a result of the recall"); *id.* 183:24-184:2 (confirming that "for the drugs that had already been used, there were no new out-of-pocket costs incurred with those"); *see generally* Complaint.) This lack of evidence is unsurprising given that "[i]n their role as insurers, TPPs experience neither health benefits nor [health] risks." (Ex. 102, Expert Report of Lauren J. Stiroh, Ph.D. ("Stiroh Rep.") ¶ 25, June 28, 2023.)

128. Dr. Conti recently testified that any product that "has a market price . . . must have some . . . economic value." (Ex. 103, Class Representative Deposition of Rena Conti ("Conti Class Rep. Dep.") 26:2-9, July 13, 2023; *see also id.* 20:9-22:1; *id.* 29:15-30:9.)

129. Dr. Conti also testified that the "clinical benefit of a product affect[s] its economic value" and "by definition" is "reflected in the demand curve" of the product. (Ex. 103, Conti Class Rep. Dep. 110:11-18.)

130. There is no evidence that the TPPs would have saved money if they had purchased an alternative hypertension drug other than the VCDs at issue at the time, and in fact it is likely alternative drugs would have been more expensive. (Ex. 102, Stiroh Rep. ¶ 64 & Fig. 4; Ex. 104, Deposition of Lauren Stiroh 63:6-66:16, Aug. 9, 2023.)

Dated: December 22, 2023

Respectfully submitted,

By: */s/ Jessica Davidson*
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on December 22, 2023, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ *Jessica Davidson*
Jessica Davidson